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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,876	08/29/2003	Kenneth F. Bastow	5470.395	9346

20792 7590 09/01/2006

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EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/651,876	BASTOW ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-9 are drawn to a method of treating a *beta*-herpes virus infection in a subject in need thereof, wherein said method comprises administering to said subject a therapeutically effective amount of a compound of Formula I, as classified in class 424, subclass 230.1.

II. Claims 10-20 are drawn to a method of treating an *alpha*-herpes virus infection in a subject in need thereof, wherein said method comprises administering to said subject a therapeutically effective amount of a compound of Formula II, as classified in class 424, subclass 231.1.

1. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 802.01 and 806.06. In the instant case, the method claimed in Invention I has a function and effect of treating a *beta*-herpes virus infection in a subject via the administration of a compound of Formula I to said subject, whereas the method claimed in Invention II has a function and effect of treating an *alpha*-herpes virus infection in a subject via the administration of a compound of Formula II to said subject, wherein the compound of Formula I is patentably distinct from the compound of Formula II because they possess different molecular structures, as well as different physicochemical properties. As a result, the method claimed in Invention I has a materially different function and effect from the method claimed in Invention II, and are therefore unrelated.

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the prior art search required for each respective invention would be divergent, thereby causing an undue search burden. As a result, restriction for examination purposes as indicated is proper. Applicants are therefore required under 35 U.S.C. § 121 to elect a single invention for prosecution on the merits.

2. Claims 1, 2, 10 and 11 are generic to a plurality of disclosed patentably distinct species of disease caused by herpesvirus of the Family Herpesviridae comprising: 1. herpes simplex virus (i.e., HSV-1 and HSV-2) of the Subfamily Alphaherpesvirinae, Genus Simplexvirus; 2. HHV-3 (a.k.a., varicella zoster virus) of the Subfamily Alphaherpesvirinae, Genus Varicellovirus; 3. CHV-1 (a.k.a., canine herpesvirus simiae) of the Subfamily Alphaherpesvirinae, Genus Varicellovirus; 4. HHV-5 (a.k.a., cytomegalovirus) of the Subfamily Betaherpesvirinae, Genus Cytomegalovirus; 5. HHV-6 (a.k.a., roseolovirus) and HHV-7 of the Subfamily Betaherpesvirinae, Genus Roseolovirus; and 6. HHV-8 (a.k.a., rhadinovirus) of the Subfamily Gammaherpesvirinae, Genus Rhadinovirus. It should be noted however that rhadinovirus is in fact a *gamma*-herpes virus and not an *alpha*-herpes virus as instantly claimed. The disclosed species of herpesvirus are patentably distinct, each from the other, because they are classified in different subfamilies, genera, and species as indicated hereinabove. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicants are further required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of herpesvirus (i.e., herpes simplex virus, namely HSV-1 and HSV-2) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 2, 10 and 11 are generic.

3. Claims 1 and 3-9 are generic to a plurality of disclosed patentably distinct species of a compound of Formula I, wherein said compound of Formula I comprises the following patentably distinct subspecies, as defined within each respective substituent and/or moiety: 1. R^1 (e.g., a hydrogen atom or an alkyl group); 2. R^2 (e.g., a hydrogen atom or an alkyl group); 3. X^1 (e.g., an oxygen atom or a sulfur atom); 4. X^2 (e.g., an oxygen atom or a sulfur atom); 5. X^3 (e.g., an oxygen atom or a sulfur atom); 6. X^4 (e.g., an oxygen atom or a sulfur atom); 7. Y (e.g., a nitrogen, oxygen, sulfur or carbon atom); 8. R^3 (e.g., a hydrogen atom or an alkyl group); and 9. R^4 (e.g., a hydrogen atom or an alkyl group). The disclosed subspecies, as defined within each respective substituent and/or moiety, are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, in the event that Applicants elect Invention I for prosecution on the merits, Applicants are required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of a compound of Formula I, by defining a single specific patentably distinct subspecies for each respective substituent and/or moiety selected from the group consisting of: 1. R^1 (e.g., a methyl group); 2. R^2 (e.g., a methyl group); 3. X^1 (e.g., an oxygen atom); 4. X^2 (e.g., an oxygen atom); 5. X^3 (e.g., an oxygen atom); 6. X^4 (e.g., an oxygen atom); 7. Y (e.g., a nitrogen atom); 8. R^3 (e.g., a methyl group); and 9. R^4 (e.g., a methyl group), for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1 and 3-9 are generic. In addition to including a listing of all claims, as well as any claims subsequently added thereto, which are readable upon the elected species, Applicant should also include a chemical structure of the elected compound, if a chemical structure of said compound is not already contained within the instant specification. If Applicant is unable to provide the chemical

structure of said compound, the CAS (Chemical Abstract Service) number assigned to said compound will suffice.

4. Claims 10 and 12-20 are generic to a plurality of disclosed patentably distinct species of a compound of Formula II, wherein said compound of Formula II comprises the following patentably distinct subspecies, as defined within each respective substituent and/or moiety: 1. R^1 (e.g., a hydrogen atom, an alkyl group, a hydroxy group, an alkoxy group, or a halogen atom); 2. R^2 (e.g., a hydrogen atom, an alkyl group, a hydroxy group, an alkoxy group, or a halogen atom); 3. W (e.g., a nitrogen atom or a CR^5 group); 4. R^5 (e.g., a hydrogen atom, a hydroxy group, an alkyl group, an alkoxy group, or a halogen atom); 5. X^3 (e.g., an oxygen atom or a sulfur atom); 6. X^4 (e.g., an oxygen atom or a sulfur atom); 7. Y (e.g., a nitrogen, oxygen, sulfur or carbon atom); 8. R^3 (e.g., a hydrogen atom or an alkyl group); and 9. R^4 (e.g., a hydrogen atom or an alkyl group). The disclosed subspecies, as defined within each respective substituent and/or moiety, are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, in the event that Applicants elect Invention II for prosecution on the merits, Applicants are required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of a compound of Formula II, by defining a single specific patentably distinct subspecies for each respective substituent and/or moiety selected from the group consisting of: 1. R^1 (e.g., a methyl group); 2. R^2 (e.g., a methyl group); 3. W (e.g., a CR^5 group); 4. R^5 (e.g., a methyl group); 5. X^3 (e.g., an oxygen atom); 6. X^4 (e.g., an oxygen atom); 7. Y (e.g., a nitrogen atom); 8. R^3 (e.g., a methyl group); and 9. R^4 (e.g., a methyl group), for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently,

claims 10 and 12-20 are generic. In addition to including a listing of all claims, as well as any claims subsequently added thereto, which are readable upon the elected species, Applicant should also include a chemical structure of the elected compound, if a chemical structure of said compound is not already contained within the instant specification. If Applicant is unable to provide the chemical structure of said compound, the CAS (Chemical Abstract Service) number assigned to said compound will suffice.

Conclusion to Restriction Requirement

The Examiner has required restriction between unrelated methods of using claims.

Applicants are advised that a fully responsive reply to this requirement must include an explicit identification of not only a single disclosed patentably distinct species of herpesvirus (i.e., herpes simplex virus, namely HSV-1 and HSV-2), but also a single disclosed patentably distinct species of a compound of either Formula I, or Formula II, by defining a single specific patentably distinct subspecies for each respective substituent and/or moiety selected from the group consisting of: 1. R^1 (e.g., a methyl group); 2. R^2 (e.g., a methyl group); 3. X^1 (e.g., an oxygen atom) (in the event that Invention I is elected); 4. X^2 (e.g., an oxygen atom) (in the event that Invention I is elected); 5. W (e.g., a CR^5 group) (in the event that Invention II is elected); 6. R^5 (e.g., a methyl group) (in the event that Invention II is elected);7. X^3 (e.g., an oxygen atom); 8. X^4 (e.g., an oxygen atom); 9. Y (e.g., a nitrogen atom); 10. R^3 (e.g., a methyl group); and 11. R^4 (e.g., a methyl group), that is elected consonant with this requirement, and a listing of all claims, including any claims subsequently added thereto, which are readable upon the elected species. An argument that a claim is allowable or that claims are not generic is considered nonresponsive unless accompanied by an explicit election of a specific species and subspecies. See 37 C.F.R. § 1.143.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species and subspecies to

be obvious variants over one another or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

If claims are added after the election, Applicant must explicitly indicate which claims are readable upon the elected species. See MPEP § 809.02(a). Amendments submitted after final rejection are governed by 37 CFR 1.116, whereas amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an actual Inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

A telephone call was made to the attorney of record, namely Mr. Kenneth D. Sibley, Esq. on August 28, 2006, to request an oral election to the above restriction requirement, but did not result in an election being made.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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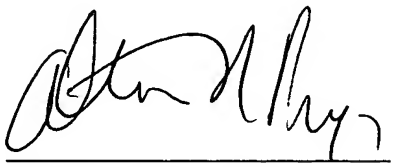

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